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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/447,227	11/22/1999	MARK C. SHULTS	MARKWELL-040	3546

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EXAMINER	
NASSER, ROBERT L	

ART UNIT	PAPER NUMBER
3735	

DATE MAILED: 08/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/447,227	SHULTS ET AL.	
	Examiner	Art Unit	
	Robert L. Nasser	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33-35,38,39,41,42,48,49 and 54-83* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33-35, 38, 39, 41, 42, 48. 49, and 54-83* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/3/2006 has been entered.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 33-35, 38, 39, 41, 42, 48, 49, and 54-83 are rejected under 35 U.S.C. 103(a) as being obvious Rhodes et al WO 92/13271 in view of Allen et al 5322063 and Picha 5706807. Rhodes shows a device in figure 2 including a housing that houses a sensor 30, 32 with an interface tip 36, with a distal first domain, i.e. surgical Dacron (polyester) fabric (see page 17 at the top) to support tissue ingrowth, a second domain, the outer membrane which is impermeable to macrophages (see page 7, lines 30-31 and pages 19+), which is made from silicone (page 22, line 16), a sensing membrane containing an enzyme (see page 7) lines 31 and 32) and a third layer that is an electrolytic phase, between the sensing layer and the sensor (see pages

7-8). Rhodes further teaches implanting the device wholly in a patient so as to elicit a foreign body capsule response, where the tip is anchored by means of a capsular attachment layer, the Dacron coating on the sides and bottom of the device. The interface tip of Rhodes does not protrude. Allen et al shows an alternate glucose sensor with a membrane layer, where the membrane layer forms a protruding tip on the sensor. Such an arrangement allows provides an increased exposed surface area of the membrane to the blood, which provides a truer picture of the overall environment of the blood. As such, it would have been obvious to modify Rhodes to use such an arrangement, to eliminate anomalies and increase the accuracy of measurement. The examiner notes that while the tip of Allen does not state that it assists in the formation of vasculature. However, it is the examiner's position that it inherently does so. The angiogenic layer does not lie on the sensing surface. However, Picha shows a similar device where such an angiogenic layer surrounds the entire sensing area. As such, it would have been obvious to modify Rhodes et al to engulf the entire device in the Dacron, as it is merely the substitution of one known configuration for another. Claim 35 is rejected in that there is further an angiogenic layer, screen 46 treated with a angiogenesis factor. Claims 38, 39, 54, and 55 are rejected for the reasons given above, noting that an angiogenic layer is a vascularization promotion layer which stimulate new vascular growth. Claim 40 is rejected in that Rhodes further teaches implanting the device wholly in a patient so as to elicit a foreign body capsule response. Claim 42 is rejected in that the device includes a transmitter for transmitting data to the exterior of the body(see page 15, line 9). Claims 48 and 49 are rejected in that the

enzyme used is glucose oxidase. With respect to claims 56-58, it is the examiner's position that given that the device of the combination has the same structure as the claimed invention, it would measure glucose accurate for the time periods. With respect to claims 59-61, applicant has admitted that it is known to explant the device when the useful life of the device is over. Claims 62-65 are rejected for the reasons given above. With respect to claims 66-69 the examiner takes official notice that all of the sensors recited are known glucose sensors. Hence, it would have been obvious to modify Rhodes to use any of the recited sensors, as it is merely the substitution of one known equivalent sensor for another. Claims 70-72, and 76-78 are rejected for the reasons given above. With respect to claims 73-75, the examiner takes official notice that it is known to explant the device when the useful life of the device is over. With respect to claims 80-83, the examiner takes official notice that all of the sensors recited are known glucose sensors. Hence, it would have been obvious to modify Rhodes to use any of the recited sensors, as it is merely the substitution of one known equivalent sensor for another.

Claims 33-35, 38, 39, 41, 42, 48, 49, and 54-83 are rejected under 35 U.S.C. 103(a) as being obvious over Allen et al in view of Rhodes et al WO 92/13271 and Picha 5706807. Allen et al shows a sensor having a base 17, having a glucose sensor mounted on the base and a membrane over the sensor. The membrane and sensor form a protruding tip the base. The membrane system does not have the structure recited in the claims. However, Rhodes et al teaches a membrane system that meets the claim language including an angiogenic layer, as discussed above, to

improve the accuracy of glucose measurement. As such, it would have been obvious to modify Allen to use the membrane structure of Rhodes, so as to improve the accuracy of measurement. The angiogenic layer does not lie on the sensing surface. However, Picha shows a similar device where such an angiogenic layer surrounds the entire sensing area. As such, it would have been obvious to modify the combination to engulf the entire device in the Dacron, as it is merely the substitution of one known configuration for another

Applicant's arguments filed 7/3/2006 have been fully considered but they are moot in view of the new grounds of rejection.

Applicant has stated that Allen is not a protruding tip. Applicant has not provided any reasoning in support of this. It appears to the examiner that the membrane protrudes from the housing and forms a tip. Hence, it is a protruding tip.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is 571 272-4731. The examiner can normally be reached on m-f 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Robert L. Nasser
Primary Examiner
Art Unit 3735

RLN
July 24, 2006

ROBERT L. NASSER
PRIMARY EXAMINER